APR - 6 2004

K040224

510(k) Summary
for
CADImplant

1. Submitter Name and Address

Praxim
"Le Grand Sablon"
4, Avenue de l'Obiou
38 700 La Tronche
France

Contact Name: Stéphane Lavallée
Telephone: 33-4 76 54 95 03

Date Prepared: October 22, 2003

2. Device Name

Proprietary Name: CADImplant™
Common/Usual Name: Pre-treatment dental software system
Classification Name: Computed tomography x-ray system (accessory)

3. Predicate Device

Columbia Scientific SimPlant (K924810)

4. Intended Use

The CADImplant software is intended for pre-treatment planning for the placement of dental implants using a CT scan which has been input into the CADImplant treatment planning software.

5. Device Description

The CADImplant software is specifically designed for use in dental implant procedures. It allows the dentist to locate dental implants on three planes (axial, sagittal and frontal) on a pre-treatment CT scan in real-time. Additionally, the software allows for the patient's prosthetic template to be pre-drilled according to the planning.

6. Technological Characteristics and Substantial Equivalence

The CADImplant software is substantially equivalent to other predicate software planning systems (e.g., Columbia Scientific SimPlant, K924810) that are currently marketed. It is similar to the other software planning systems in its technological characteristics. It uses a pre-treatment CT scan for 3-D planning as other previously cleared software planning systems. Like the predicate products, it uses accessories during the pre-treatment image acquisition and require decontamination prior to use. The various predicate software systems use a variety of methods for calibration of the alignment of the patient with an image. CADIMplant uses a Reference Cube attached to the outside of the patient's prosthetic template during image acquisition.

7. Performance Testing

The CADImplant software was tested for compliance with software standards. In addition, summaries of accuracy testing using phantoms and clinical experience with the system were provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2004

Ms. Christine Meehan
General Manager
Praxim, Inc
486 High Plain Street
WALPOLE MA 02081

Re: K040224
Trade/Device Name: CADImplant™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and Communications system
Product Code: 90 JAK and 90 LLZ
Dated: January 30, 2004
Received: February 3, 2004

Dear Ms. Meehan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040224

Device Name: CADIMPLANT
Indications for Use:

CADImplant is intended for pre-treatment software planning for the placement of dental implants using a CT scan which has been input into the CADImplant treatment planning software.

(Please do not write below this line –Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040224

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)